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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,438	11/14/2003	Douglas G. Evans	KN P 0131	9636
7590	08/11/2004		EXAMINER	
Jeffrey C. Kelly Kensey Nash Corporation 55 East Uwchlan Avenue Exton, PA 19341			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/713,438

**Applicant(s)**

EVANS ET AL.

**Examiner**

Javier G. Blanco

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>03/15/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Implant: Species A (Figure 2A) and Tissue Treatment System: Species A (Figure 1) in the reply filed on May 20, 2004 is acknowledged. All 34 claims that are presently pending are readable on both elected species.

### ***Response to Amendment***

2. Applicant's amendment of the specification (with regards to the description of Figure 3) in the reply filed on May 20, 2004 is acknowledged.

### ***Drawings***

3. The drawings are objected to because the legend for Figure 2L should be substituted with Figure 3 (see amendment filed May 20, 2004). Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the

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drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

4. Claim 30 is objected to because of the following informalities: please substitute “components” (see line 5) with --component--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 23-25 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Regarding claim 23, “the concentration of chips and granules” (see line 1) and “the construct” (see line 2) lack antecedent basis.
- b. Regarding claim 24, “the construct” (see line 2) lacks antecedent basis.
- c. Regarding claim 25, “the construct” (see line 2) lacks antecedent basis.
- d. Regarding claim 29, “the cross-sectional configuration of the cylindrical housing” (see lines 1-2) and “the channel” (see line 2) lack antecedent basis.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-34 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Yamamoto et al. (US 2002/0183855; cited in Applicants' IDS).

Yamamoto et al. disclose an implant for the repair or regeneration of tissue (see entire document). Said implant is porous, biodegradable, three-dimensionally fixed, has shape memory, and maintains physical/structural integrity and porosity after been implanted (see entire document).

At least a first component of the implant is a non-soluble ceramic microgranules/microparticulate (i.e., calcium phosphate, hydroxyapatite; see page 2, paragraph 0020; page 3, paragraph 0036). At least a second component is a non-soluble natural collagen fiber (i.e., insoluble fibrillar collagen; see page 1, paragraph 0015) obtained from either mineralized or unmineralized collagen sources (see page 2, paragraph 0015). At least a third component is a non-porous collagen gel (see page 2, paragraphs 0024-0027). Besides maintaining physical/structural integrity and porosity after been implanted, another property of the resulting matrix is the capability of been compressible from an initial size, shape, and porosity, and returning, from a compressed state, to its initial size, shape, and porosity (see page 3, paragraph 0031).

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Said matrix further comprising: proteins, growth factors, bone marrow, and drugs (see page 2, paragraph 0022; page 3, paragraph 0037). Also, said matrix is cross-linked (i.e., glutaraldehyde; see page 2, paragraph 0028; page 3, paragraph 0032) and sterilized (i.e., ethylene oxide; see page 3, paragraph 0033). The matrix or slurry can be lyophilized (see page 2, paragraph 0028) and can also be hydrated prior to or following implantation (see page 5, paragraphs 0054-0056). Further, said matrix can be compressed during the implant procedure (see page 3, paragraph 0034) or prior to the implant procedure (see page 4, paragraph 0046). The proportions of insoluble (i.e., fibrillar mineralized or unmineralized collagen) to soluble collagen are disclosed in page 2, paragraphs 0023 and 0027. The matrix can be delivered via a delivery vehicle such as a cannula (see page 3, paragraph 0034).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

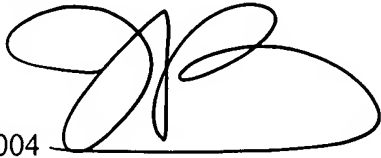
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JGB

August 6, 2004

A large, stylized handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the bottom.A handwritten signature in black ink, appearing to read 'David H. Willse', with a long horizontal stroke extending to the right.

**David H. Willse**  
**Primary Examiner**